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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,611	SWENSON ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *16-20 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Response and Request for Extension of Time filed 06/30/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 7-11, 21, 29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Bertini et al. US 6,069,172.

Bertini teaches a pharmaceutical preparation for oral administration comprising ketoprofen (see abstract). The preparation in the form of controlled release, slow-release, or immediate release comprises from 10-80% maltodextrin, and from 2-10% cellulose as binding agent (column 10, lines 1-48).

It is noted that Bertini does not teach that the cellulose and the maltodextrin slow the disintegration of the orally administered specimen to provide a sustained release of the bioactive substance. However, the limitation is clearly inherent because Bertini teaches a slow release formulation comprises cellulose in the claimed amount, and maltodextrin having the claimed ratio. Furthermore, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In this case, Bertini teaches the use of mixture of maltodextrin and cellulose in an oral dosage form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7-11, 21, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al.

Bertini is relied upon for the reason stated above. In the case that applicant can overcome the above 102(e) rejection, Bertini is relied upon for the reason that it would have been obvious for one of ordinary skill in the art to, by routine experimentation select maltodextrin as an excipient in combination with the binding agent such as cellulose material to obtain the claimed invention, because Bertini teaches a slow release formulation comprising excipient such as lactose, microcrystalline cellulose, powdered cellulose, hydrogenphosphas, silica and their mixture (column 10, lines 39-49).

Claims 21-23, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al., and Baichwal et al. US 5,128,143.

Bertini is relied upon for the reason stated above. Bertini does not teach the sustained release time period.

Baichwal teaches sustained release excipient and tablet formulation comprising active medicament; polysaccharide gum, *e.g.*, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, or carboxymethyl cellulose; and diluent, *e.g.*, microcrystalline cellulose, dextrose, or mixtures thereof (columns 6-8). The dissolution time for the active medication is within about 3.5-5 hours (column 9, lines 43-60). Hence, it would have been prima facie obvious for one of ordinary skill in the art to modify the pharmaceutical preparation of Bertini in view of the teaching of Baichwal, because the

cited references teach the advantageous results in the use of cellulose and dextrose or maltodextrin. The expected result would be a useful excipient composition, which can be blended with a wide variety of active medicaments for sustained/controlled release oral dosage form.

Claims 1, and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al. US 5,470,581.

Grillo teaches dry powder film coating composition for pharmaceutical tablet, the coating comprising from 4-90% cellulosic polymer, and from 5-78.5% maltodextrin (column 2, and abstract). The weight ratio of cellulosic polymer to maltodextrin is 3:7 (id).t is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify Grillo's composition with the expectation of at least similar result, because Grillo obtains the same formulation desire by the applicant, i.e., mixture of cellulosic polymer and maltodextrin as dry powder edible film coating composition for use in pharmaceutical tablet (abstract).

Claims 21-23, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Baichwal et al. US 5,128,143.

Grillo is relied upon for the reason stated above. Grillo does not teach the sustained release time period.

Baichwal teaches sustained release excipient and tablet formulation comprising active medicament; polysaccharide gum, *e.g.*, hydroxypropylmethyl cellulose,

hydroxypropyl cellulose, or carboxymethyl cellulose; and diluent, *e.g.*, microcrystalline cellulose, dextrose, or mixtures thereof (columns 6-8). The dissolution time for the active medication is within about 3.5-5 hours (column 9, lines 43-60). Hence, it would have been prima facie obvious for one of ordinary skill in the art to modify Grillo's coating composition for pharmaceutical tablet in view of the teaching of Baichwal, because the cited references teach the advantageous results in the use of cellulose and dextrose or maltodextrin. The expected result would be a useful excipient composition, which can be blended with a wide variety of active medicaments for sustained/controlled release tablet dosage form.

Claims 2-6, 33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertini et al., and Lord et al. US 6,417,227.

Bertini is relied upon for the reasons stated above. Bertini teaches the use of medicament, but silent as to the teaching of the specific medicament being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Lord's formulation using the excipient in view of the teaching of Bertini, because the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 2-6, 33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Lord et al. US 6,417,227.

Grillo is relied upon for the reasons stated above. Grillo teaches the use of medicament, but silent as to the teaching of the specific medicament being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Lord's formulation using the coating excipient in view of the teaching of Grillo, because the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 14, 15, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., in view of Lord et al., and Grain processing Corporation.

Grillo and Lord are relied upon for the reasons stated above. The references are silent as to the teaching of the claimed maltodextrin.

Grain processing corporation teaches maltodextrin, such as Maltrin® having no protein, fat, or fiber, which is commonly used in consumer products as dry mixes (pages 1-2). Hence, it would have been obvious for one of ordinary skill in this art to modify Grillo's maltodextrin using Maltrin® in view of the teaching of Grain processing

Corporation. The reason for this modification is to obtain an excellent dry powder edible film coating composition for use in pharmaceutical, food and confectionery forms.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Baichwal et al., and Lord et al.

Regarding to claims 24-28, Grillo and Baichwal do not teach the specific active agent.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the compositions of Grillo and Baichwal with the active agents in view of Lord's teaching to obtain the claimed invention, since the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Bertini et al.

Grillo is relied upon for the reasons stated above. Grillo does not teach the claimed cellulose polymer.

Bertini teaches excipient composition for controlled release oral dosage form comprising maltodextrins and powdered cellulose. Although Bertini does not teach the

polymerization degree range of cellulose, it is the examiner's position that, it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable cellulose powder to obtain a desirable dry powder coating composition.

Response to Arguments

Applicant's arguments filed 06/30/04 have been fully considered but they are not persuasive. Original rejections are maintained.

Applicant argues that Bertini does not teach or disclose the claimed range of cellulose or the ratio of cellulose to maltodextrin. Contrary to the applicant's argument, applicant's attention is called to column 10, lines 39-49, supporting mass material consists of excipients such as maltodextrin can constitute up to 80% by weight of the formulation, and binding substances such as cellulose is present at a concentration of from 2-10% of the formulation. Thus, the amount of cellulose would fall within the claimed range of from about 4% to about 14%, as well as the ratio between cellulose and maltodextrin would fall within the claimed range of 1:9 (2-10%:80%). Accordingly, Bertini does disclose the claimed range of cellulose and the ratio of cellulose to maltodextrin.

Applicant argues that Bertini does not teach or disclose the combination of cellulose and maltodextrin. Bertini merely includes a list of potential ingredients to be used as a supporting mass, and the list includes cellulose and maltodextrin among many others as potential excipients. However, as discussed above, Bertini requires the use of binding substance, including cellulose material in the amount of from 2-10%.

Maltodextrin is listed in the list of six other excipients that can be used as the supporting mass in the amount from 10-80%. Bertini also discloses the supporting mass can be used as a mixture (or alternatively) (ID). The list of 7 excipients to chose from is not indefinite. Moreover, maltodextrin is a well known excipient in pharmaceutical art (see Dunn et al. at column 7, lines 38-39 for reference).

Applicant argues that Baichwal cannot cure the deficiencies of Bertini, Baichwal only teaches the use of heteropolysaccharide and optional inert filler. As discussed above, Bertini does disclose the combination of maltodextrin and cellulose in the claimed amount and ratio. Baichwal is cited solely for the teaching of the release period of at least one hour.

Applicant argues that Grillo is entirely focused on coatings, and there is no suggestion or motivation anywhere in Grillo to move from making "coatings" and optimizing the properties of the "coatings" to making a release composition fro use as an excipient of an orally administered specimen to be mixed with a bioactive substance. Contrary to the applicant's argument, it is noted that it is the composition that is being claimed. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The claimed composition comprises active substance, cellulose, and maltodextrin, wherein upon mixing the ingredients, the cellulose and the maltodextrin slow the disintegration to provide a sustained release of the active substance. Nowhere

in the claims exclude/prevent the cellulose and maltodextrin to coat and/or encapsulate the active substance such that it provide a sustained release of the active substance. Applicant argues that Grillo in no way teaches or suggests the use of cellulose and maltodextrin to obtain sustained release features. In response to applicant's argument, the burden is shifted to applicant to provide data showing the edible coating comprising maltodextrin and cellulose taught by Grillo does not exhibit sustained release properties. See *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).

Applicant argues that there is no suggestion to combine Grillo and Baichwal because neither Grillo nor Baichwal teach or suggest that the combination of cellulose and maltodextrin would function as a sustained release excipient. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Baichwal is relied upon solely for the teaching of the sustained release profile.

Applicant argues that there is no suggestion in either reference that the proposed modification, taken from Baichwal, would make Grillo satisfactory for its intended purpose of applying "coatings" of achieving coatings or coating films that have the desired properties taught by Grillo. Therefore, the proposed combination does not

teach all the recited limitations in independent claim 21. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that Grillo is focused on coatings and coating films. Lord on the other hand is concerned with coating or enteric coating to prevent the cetyl myristoleate from being released in the stomach. Therefore, the proposed combination would destroy the intended purpose of Lord and is not permissible. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lord is relied upon solely for the teaching of the claimed medicament, which can be in a delayed dosage form.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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